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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/779,455 | 02/09/2001 | Tarun K. Dhar | 056859/0115 | 6699 |

22428 7590 02/13/2003

FOLEY AND LARDNER
SUITE 500
3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

NGUYEN, BAO THUY L

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| ART UNIT | PAPER NUMBER |
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1641

DATE MAILED: 02/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/779,455

Applicant(s)

DHAR ET AL.

Examiner

Bao-Thuy L. Nguyen

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1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 22-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group 1, claims 1-21 in Paper No. 6 is acknowledged.
2. Claims 22-43 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 6.
3. This application contains claims drawn to an invention nonelected with traverse in Paper No. 6. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Claim Rejections - 35 USC § 112

4. Claims 1-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite with respect to the description of the absorbent material. Because the absorbent material is recited as being provided separately, it is unclear how this absorbent material relates to the analytical device as claimed. The function of the absorbent material is also unclear. It appears that Applicant is attempting to claim a kit comprising different components, one of which is the absorbent body. If this is the case, the claim should be amended for clarity.

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Claim 2 is vague and indefinite because of the recitation of "alternately comprising" because it is unclear which component of the device is provided as an alternative. Does Applicant mean -optionally--?

Claim 3 is vague and indefinite with respect to the recitation of "much smaller" because it is unclear how "much" is defined.

Claim 4 appears to recite some kind of contact between the absorbent body and the device, however the recitation of separately provided is confusing.

Claim 7 is vague and indefinite because it does not have positive nor negative limitations.

Claim 10 is vague and indefinite because it appears to lack antecedent support. The average diameter of the membrane is claimed, yet the reaction membrane has not been introduced as being circular.

Claim 11 is vague and indefinite because "the loose area" lacks antecedent support. The recitation of "under certain circumstances" is vague because it is unclear what these circumstances are.

Claim 12 is vague and indefinite with respect to the recitation of "it is capable of immobilizing" because it is not a positive limitation. Does the membrane have the antibodies immobilized thereon or is it only capable of immobilizing the antibodies?

Claim 14 is vague and indefinite because the recitation of "for ultrasensitive format" does not appear to be positive limitation of the claim. In essence, the compounds being claimed are not an essential component of the device. Claim 14 is also vague and indefinite with respect to the recitation of "and other similar materials" because it is unclear what constitute similar materials. "p-hydroxy-phenylpropionic acid" is misspelled.

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Claim 21 is vague and indefinite because it appears to recite a use of the absorbent body and thus is not a positive limitation of the assay device.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. Claims 1-12 and 15-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown et al (US 5,807,522) in view of Lin et al (US 6,265,176).

Brown discloses a substrate formed of a water-impermeable backing having thereon a porous membrane. The porous membrane is applied to the backing by a variety of methods including heat-seal stamping, laminating or via adhesives (column 12). Ligands such as antigen or antibody is applied in a spotted array onto the membrane (columns 6 and 15).

Brown differs from the instant invention in failing to teach a body of absorbent material provided separately.

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Lin, however, discloses analytical test kits and method comprising test cards or strips of an inert plastic carrier having a flat, non-absorbent surface having antigen or antibody spotted thereon. The spots on the card may be more than one reagent for testing for multiple unknowns. During use, the spot is washed and blotted dry using absorbent blotting papers. Lin teaches test kits comprising the carrier and blotting papers.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Brown because such blotting papers are well known in the art. The use such blotting papers provides the advantage of a shorter assay time because test cartridges may be blotted dry instead of air dry thus reducing the time needed and optimizing assay conditions.

8. Claims 1, 3-13, 15 and 18-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kearns et al (US 5,573,919) in view of Lin et al (US 6,265,176).

Kearns discloses an assay for detecting analyte comprising absorbent contained in a casing made of plastic. The absorbent membrane has a porosity such that it can retain particles having a size of about 0.1 micron to 10 microns. See column 2, line 41 through column 2, line 11; and column 3, lines 17 through column 4, line 17. Kearns teaches coating the surface with BSA to prevent non-specific binding. See column 6, lines 8-20 and 44-57.

Kearns differs from the instant invention in failing to teach a body of absorbent material provided separately.

See the discussion of Lin above.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to include the blotting papers taught by Lin in the test system and kit of Kearns because such blotting papers are well known in the art. The use such blotting papers

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provides the advantage of a shorter assay time because test cartridges may be blotted dry instead of air dry thus reducing the time needed and optimizing assay conditions.

Allowable Subject Matter

9. Claim 14 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: the prior art of record fail to disclose the use of p-hydroxy-phenylprionic acid-casein and p-hydroxy-phenylpropionic acid-gelatin conjugates as blocking solution in an array comprising multiple spotted regions of antigens or antibodies.

Conclusion

10. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

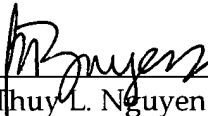
US 4,235,601
US 4,246,339
US 4,518,565
US 4,727,037
US 4,990,442
US 5,059,522
US 5,098,846
US 5,202,432
US 5,270,167
US 5,486,452
US 5,569,589
US 6,045,753
US 6,372,515
US 6,406,922
US 6,514,769 B2
GB 2,342,443

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (703) 308-4243. The examiner can normally be reached on Monday, Wednesday and Thursday from 9:00 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (703) 305-3399. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 for regular communications and (703) 308-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Bao-Thuy L. Nguyen
Primary Examiner
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February 6, 2003